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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,721	09/09/2003	Russell A. Houser	1208.001	3898

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,721	HOUSER ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *1-10,15,18-22,28-37,43,44,46-49 and 55-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14,16,17,23-27,38-42,45 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II: Claims 11-14, 16, 17, 23-27, 38-42, 45, and 50-54 in the reply filed on 12/15/06 is acknowledged.

Claims 1-10, 15, 18-22, 28-37, 43, 44, 46-49, and 55-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/15/06.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 recites the limitation "withdrawing the catheter and guidewire" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim. Applicant neither discloses a catheter prior to this, nor discloses the insertion of a catheter in the first place. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ernst et al. (US 5,403,278).

5. With respect to Claim 11, Earnst discloses a method of draining a pseudo aneurysm and sealing the related blood vessel comprising the steps of inserting a needle, advancing a guide wire through the needle, and advancing a catheter/sheath over the guide wire (Column 2, Lines 28-56). Prior to withdrawing the catheter and guide wire, the pseudo aneurysm is drained until the bleeding has stopped (Column 3, Lines 47-49). Additionally, a contrast media may be introduced (Column 2, Lines 22-27). Claim 11 does not disclose any steps with regard to a sealing method.

6. With respect to Claim 12, Earnst et al. disclose the step of injecting collagen, a coagulant, to aid in clotting of a puncture in the blood vessel (Column 1, Lines 35-45).

7. With respect to Claim 13, Earnst et al. disclose that said blood vessel is an artery (Column 1, Lines 35-38).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 14, 16, 17, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernst et al. in view of Gershony et al. (US 5,868,778).

11. With respect to Claims 14, 16, and 17, Ernst et al. disclose the method of Claim 11, but do not disclose a that the catheter comprises a shaft reinforcing component. Gershony et al. disclose a vascular sealing method wherein the catheter comprises a core wire 17 that is interpreted as being capable of acting as a shaft reinforcing component. However, the core wire 16 tapers off toward the distal end of the catheter in order to allow for flexibility of the distal portion 16 (see Figure 1). Therefore, the it is the examiner's interpretation that the "shaft reinforcing component" comprises only the proximal portion of the core wire 17, and therefore extends along less than the entire length of the catheter, as per Claim 16. Furthermore, Said shaft reinforcing component is sufficiently mandrel-shaped, as per Claim 17. Furthermore, the reaccess sheath 49 further reinforces the shaft (see Figure 1). It would have been obvious to one skilled in the art at the time of invention to modify the method of Ernst et al. with the reinforced catheter shaft of Gershony et al. in order to improve the maneuverability of the catheter once it is inserted and assist in the deflation of the balloon and subsequent removal of the catheter, as well as allow for flexibity at the distal end of the catheter while keeping the proximal portion rigid (see Figures 1-3 of Gershony et al.).

12. With respect to Claims 23 and 24, Ernst et al. discloses the method of Claim 11, but does not disclose that the distal and proximal sections of the catheter are made of different materials. Gershony et al. disclose a vascular sealing apparatus and method comprising a catheter which has a distal end 16 that is made of a different material than the proximal section 13. The proximal

section 13 is made of a plastic material (Column 3, Line 66 through Column 4, Line 11), while the distal section 16 is made of platinum wire (Column 5, Lines 31-32). Furthermore, Gershony et al. disclose that the distal portion 16 of the catheter is more atraumatic than the material of the proximal section, as per Claim 51 (Column 5, Lines 26-35). It would have been obvious to one skilled in the art at the time of invention to combine the method of draining and sealing a pseudo aneurysm of Ernst et al. with the catheter having an atraumatic distal end of Gershony et al. in order to reduce pain while the catheter is being inserted. Because both inventions disclose methods of sealing vascular leaks, it would have been obvious to apply an atraumatic tip, which is well known in the art, to the catheter of Ernst et al.

13. With respect to Claim 25, Ernst et al. disclose the method of Claim 11, but do not disclose that the collagen material injected is too viscous to seep through the vessel puncture. Gershony et al. disclose that the catheter injects a coagulant material (collagen) that has viscous properties, and therefore will not seep through the vessel puncture (Column 8, Lines 60-61). Allowing the coagulant to enter the blood stream could cause undesired clotting. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the method of Ernst et al. with the viscous coagulant injection of Gershony et al. in order to prevent the blood vessel to develop blood clots, thereby restricting blood flow.

14. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernst et al. in view of Hart et al. (5,868,708). Ernst et al.

disclose the method of Claim 11, but does not disclose that the catheter comprises a shaped profile having an hourglass or peanut shape. Hart et al. disclose a catheter apparatus comprising a distal portion that may comprise many shapes, including a hourglass/peanut shape (see Fugures 7-11). The two bulges of the hourglass shape effectively secure the distal end of the catheter on both sides of the vessel puncture. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the method of Ernst et al. with the catheter shape of Hart et al. in order to prevent the catheter from moving in either direction while the coagulant is being applied to the vessel.

15. Claims 38-41 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershony et al. in view of Ernst et al.

16. With respect to Claim 38, Gershony et al. disclose a method of sealing a blood vessel comprising inserting a needle into the blood vessel, advancing a guide wire through the needle, advancing a catheter over the guide wire, and withdrawing the catheter when the procedure is complete (Column 1, Lines 23-32). Gershony et al. further disclose that the catheter comprises a contrast media 45 that will be inserted into the pseudo aneurysm when the catheter is inserted. Gershony et al., however, do not disclose a the step of draining the pseudo aneurysm sack before the catheter is withdrawn. Ernst et al. disclose a method of treating a pseudo aneurysm comprising sealing the blood vessel, as well as draining the pseudo aneurysm sack (Column 3, Lines 47-49). While the method of Ernst et al. seals the blood vessel in a materially different manner, the same task is being accomplished along with the additional functionality of

draining the pseudo aneurysm. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the sealing method of Gershony et al. with the draining step of Ernst et al. in order to simultaneously drain the pseudo aneurysm and prevent it from refilling.

17. With respect to Claim 39, while Gershony et al. does not expressly disclose that said blood vessel is an artery, the cited reference material refers to arteries, implying that disclosed method is intended to be used on arteries. Furthermore, Gershony et al. disclose the use of a catheter on atherosclerotic blood vessels, which implies that said vessels are arteries (Column 1, Lines 15-23).

18. With respect to Claim 40, Gershony et al. disclose the step of injecting a coagulant to aid in clotting of a puncture in the blood vessel (Column 2, Lines 13-26).

19. With respect to Claim 41, Gershony et al. disclose that the catheter comprises a shaft reinforcing component 17.

20. With respect to Claims 50 and 51, Gershony et al. further disclose a vascular sealing apparatus and method comprising a catheter which has a distal end 16 that is made of a different material than the proximal section 13. The proximal section 13 is made of a plastic material (Column 3, Line 66 through Column 4, Line 11), while the distal section 16 is made of platinum wire (Column 5, Lines 31-32). Furthermore, Gershony et al. disclose that the distal portion 16 of the catheter is more atraumatic than the material of the proximal section, as per Claim 51 (Column 5, Lines 26-35).

21. With respect to Claim 52, Gershony et al. disclose the step of injecting a material that is viscous, and therefore will not seep through the vessel puncture (Column 8, Lines 60-61).

22. With respect to Claim 53, Gershony et al. disclose that the catheter shaft comprises a shaped profile (balloon portion) 15 on which the resistance is capable of being varied by means of changing the air pressure in the balloon (via the inflation port 31).

23. Claims 42, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershony et al. in view of Ernst et al., and further in view of Behl et al. (US 5,709,224). Gershony et al. in view of Ernst et al. disclose the method of Claims 38 and 41, but do not that the reinforcing component extends the entire length of the catheter or that the reinforcing component is a hypo tube. Behl et al. disclose a catheter for the treatment of a blood vessel comprising a hypo tube that extends the entire length of the catheter. It would have been obvious to one skilled in the art to combine the method and catheter of Gershony et al. in view of Ernst et al. with the hypo tube of Behl et al. in order to provide a catheter that has is rigid over the entirety of the shaft. Because the entire shaft would be rigid, the distal end of the catheter could be easily positioned over the vessel puncture and maneuvered as needed during treatment.

24. Claim 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershony et al. in view of Ernst et al., and further in view of Hart et al. Gershony et al. in view of Ernst et al. disclose the method of Claims 38 and 53, but do not disclose that the shaped profile has an hourglass or peanut shape. Hart et al.

disclose a catheter apparatus comprising a distal portion that may comprise many shapes, including a hourglass/peanut shape (see Fugures 7-11). The two bulges of the hourglass shape effectively secure the distal end of the catheter on both sides of the vessel puncture. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the method of Gershony et al. in view of Ernst et al. with the catheter shape of Hart et al. in order to prevent the catheter from moving in either direction while the coagulant is being applied to the vessel.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
2/2/07

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PRIMARY EXAMINER